

510(k) Summary of Safety and Effectiveness

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR807.92 (a) (1)]

December 30, 2012

2. Submitter's Information [21 CFR807.92 (a) (1)]

Name of Sponsor:

SonoScape Company Limited

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3. Trade Name, Common Name, Classification [21 CFR807.92(a)(2)]

Trade Name:

S2 Portable Digital Color Doppler Ultrasound System

Common Name:

Diagnostic Ultrasound System and Transducers

Classification:

21 CFR892.1550 Ultrasonic Pulsed Doppler Imaging System

Product code: IYN

21 CFR892.1560 Ultrasonic Pulsed Echo Imaging System

Product code: IYO

21 CFR892.1570 Diagnostic Ultrasonic Transducer

Product code: ITX

Classification Panel:

Radiology

Device Class:

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4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicates within this submission are as follows:

SonoScape Company Limited, Diagnostic Ultrasound System, Model S6 has been cleared by FDA through 510(k) No.K112602 (Decision Date – November 07, 2011).

5. Description of the Device [21 CFR 807.92(a)(4)]

The SonoScapeS2 Portable Digital Color Doppler Ultrasound System is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in-depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features.

This SonoScape system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound data and display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Doppler and Power Doppler, or a combination of these modes, 4D.

6. Intended Use [21 CFR 807.92(a)(5)]

The SonoScape S2 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

Table 1 Transducer Information

| No. | Probe | Туре | Frequency Range | Intended Use |
|-----|-------|--------------|--------------------|-------------------|
| 1 | 2P1 | Phased Array | 2.0-4.0 MHz | Abdominal |
| | | | | Neonatal Cephalic |

| No. | Probe | Туре | Frequency Range | Intended Use |
|-----|-------|--------------|--------------------|-------------------------------------|
| | | | | Adult Cephalic |
| | | | | Cardiac Adult |
| | | | | Cardiac Pediatric |
| 2 | 5P1 | Phased Array | 4.0-7.0 MHz | Pediatric |
| | | | | Neonatal Cephalic |
| | | | | Cardiac Pediatric |
| 3 | 6V1 | Micro-curved | 4.0-8.0 MHz | Trans-rectal |
| | | Array | | Trans-vaginal |
| 4 | 6V3 | Micro-curved | 5.0-9.0 MHz | Trans-rectal |
| | | Array | | Trans-vaginal |
| 5 | EC9-5 | Micro-curved | 5.0-9.0 MHz | Trans-rectal |
| | | Array | | Trans-vaginal |
| 6 | C611 | Micro-curved | 4.0-8.0 MHz | Abdominal |
| | | Array | | Pediatric |
| | | | | Neonatal Cephalic |
| | | | | Cardiac Pediatric |
| 7 | C344 | curved Array | 2.0-5.0 MHz | Fetal / Abdominal/ Ob/GYN |
| 8 | C362 | curved Array | 2.0-6.0 MHz | Fetal / Abdominal/ Ob/GYN |
| 9 | VC6-2 | curved Array | 2.0-6.0 MHz | Fetal / Abdominal/ Ob/GYN |
| 10 | L741 | Linear Array | 5.0-10.0 MHz | Small Organ (reast, thyroid,testes) |
| | | | | Musculo-skeletal (Conventional) |
| | | | | Peripheral vessel |
| 11 | L742 | Linear Array | 5.0-12.0 MHz | Small Organ (reast, thyroid,testes) |
| | | | | Musculo-skeletal (Conventional) |
| | | | | Musculo-skeletal (Superficial) |
| | | | | Peripheral vessel |
| 12 | L743 | Linear Array | 5.0-10.0 MHz | Small Organ (reast, thyroid,testes) |
| | | | | Musculo-skeletal (Conventional) |
| | | | | Musculo-skeletal (Superficial) |
| | | | | Peripheral vessel |
| 13 | C354 | curved Array | 2.0-5.0 MHz | Fetal / Abdominal/ Ob/GYN |



8. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92]

Safety Considerations:

The S2 Portable Digital Color Doppler Ultrasound System with added transducer incorporates the same fundamental technology as the predicate device. The device has been tested as Track 3 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers "issued September 9, 2008. The acoustic output is measured and calculated per NEMA UID 2: 2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment and NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment. The device conforms to applicable medical device safety standards, such as IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, ISO10993-5and ISO 10993-10.

Testing:

Laboratory testing was conducted to verify that the S2 Portable Digital Color Doppler Ultrasound System with added transducer met all design specification and was substantially equivalent to the currently marketed Predicate Device as above. The device has been found to conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility. Acoustic output is measured and calculated according to "Acoustic Output Measuring Standard for Diagnostic Ultrasound Equipment".

Tab 2 Applicable Safety Standards

| Standards No. | Standards Title | Version | Date |
|------------------|--|----------|------------|
| IEC 60601-1 | Medical Electrical Equipment - Part1. | 1988+A1: | 10/31/2005 |
| | General Requirements for Safety | 1991+A2: | |
| | | 1995 | |
| IEC | Medical Electrical Equipment, Part 1-2: | 2007 | 03/01/2007 |
| 60601-1-2 | General Requirements for Safety - | , | |
| | Collateral Standard: Electromagnetic | | |
| | Compatibility – Requirements and Tests | | |
| IEC | Medical Electrical Equipment, Part 2-37: | 2007 | 08/01/2007 |

| 60601-2-37 | Particular Requirements for the Safety of | | |
|-------------|--|------|------------|
| | Ultrasonic Medical Diagnostic and | | |
| | Monitoring Equipment | | |
| NEMA UD 2 | Acoustic Output Measurement Standard for | 2004 | 01/01/2004 |
| | Diagnostic Ultrasound Equipment Version 3 | | (R 2009) |
| NEMA UD3 | Standard for Real-Time Display of Thermal | 2004 | 01/01/2004 |
| | and Mechanical Acoustic Output Indices on | | (R 2009) |
| | Diagnostic Ultrasound Equipment | | |
| ISO 10993-5 | Biological evaluation of medical devices - | 1999 | 09/12/2007 |
| | Part 5: Tests for In Vitro cytotoxicity | | |
| ISO | Biological evaluation of medical devices - | 2002 | 09/01/2002 |
| 10993-10 | Part 10: Tests for irritation and delayed-type | | |
| | hypersensitivity | , | |

Results of performance and compliance testing conducted on the S2 Portable Digital Color Doppler Ultrasound System, indicates conformance to all applicable standards recognized by FDA for this device.

Based on non-clinical test results, S2 Portable Digital Color Doppler Ultrasound System is substantially equivalent to predicate devices in safety and effectiveness.

9. Conclusion [21 CFR 807.92(b) (3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, SonoScape Company Limited concludes that S2 Portable Digital Color Doppler Ultrasound System is substantially equivalent to predicate devices with regard to safety and effectiveness.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

April 12, 2013

SonoScape Company Limited % Miss Toki Wu Official Correspondent Yizhe Building, Yuquan Road Nanshan, Shenzhen 518051 P.R. CHINA

Re: K130119

Trade/Device Name: S2 Portable Digital Color Doppler Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX Dated: December 28, 2012 Received: February 20, 2013

Dear Miss Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the <u>S2 Portable Digital Color Doppler Ultrasound System</u>, as described in your premarket notification:

Transducer Model Number

| 2P1 Phase Array | C344 Curved Array |
|--------------------------|--------------------|
| 5P1 Phase Array | C354 Curved Array |
| 6V1 Micro-curved Array | VC6-2 Curved Array |
| 6V3 Micro-curved Array | L743 Linear Array |
| EC9-5 Micro-curved Array | L741 Linear Array |
| C611 Micro-curved Array | L742 Linear Array |
| C362 Curved Array | • |

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris

Smh. 7.

Director, Division of Radiological Health

for

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K130119 Device Name: S2 Portable Digital Color Doppler Ultrasound System Indications for Use: The SonoScape S2 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology. Prescription Use AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) (Division Sign-Off) Division of Radiological Health Office of In Vitro Diagnostics and Radiological Health

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510(k) <u>K130119</u>

System: SonoScape S2

Diagnostic Ultrasound Pulsed Echo System

Diagnostic Ultrasound Pulsed Doppler Imaging System

| Clinical App | olication | М | ode o | of Opera | tion | | · · · · · · · · · · · · · · · · · · · | | |
|------------------------------|------------------------------------|---|-------|----------|------|---------------------------------------|---------------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | В | м | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| | Fetal | Ρ | Р | Ρ | | P | Р | Note 1 | Notes 2,4 |
| | Abdominal | Ρ | Р | Р | | P | Р | Note 1 | Notes 2,4 |
| | Intra-operative Specify : | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | , | |
| | Pediatric | Р | . P | Р | | P | Р | Note 1 | Notes 2 |
| Fetal Imaging& | Small Organ (specify) | P | Р | P | | Р | Р | Note 1 | Notes 2,5 |
| | Neonatal Cephalic | Р | Р | Р | Р | Р | Р | Note 1 | Notes 2,3 |
| | Adult Cephalic | Р | Р | Р | Р | P | р | Note 1 | Notes 2,3 |
| | Trans-rectal | Р | Р | Р | _ | Р | Р | Note 1 | Notes 2 |
| Other | Trans-vaginal | P | Р | Р | | Р | Р | Note 1 | Notes 2 |
| | Trans-urethral | | | | | | - | | |
| | Trans-esoph.(non-Card) | | | | | · · · · · · · · · · · · · · · · · · · | | | |
| | Musculo-skeletal (Conventional) | Р | Р | Р | | P | Р | Note 1 | Notes 2 |
| | Musculo-skeletal (Superficial) | P | P | Р | | Р | Р | Note 1 | Notes 2 |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | Ρ | Р | Р | | Р | Р | Note 1 | Notes 2,4 |
| | Cardiac Adult | Р | Р | Р | Р | Р | Р | Note 1 | Notes 2,3 |
| | Cardiac Pediatric | Р | Р | Р | Р | Р | Р | Note 1 | Notes 2,3 |
| Cardiac | Intravascular(Cardiac) | | | | | | | | <u> </u> |
| Calulac | Trans-esoph (Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | · | | | |
| Peripheral | Peripheral vessel | Р | Р | Р | | Р | Р | Note 1 | Notes 2 |
| Vessel | Other (specify) | | | | | | | 12.V | |

| Vessel | Other (specify) | | | | | | |
|--|--|-------------------------------|--|----------------------|-------------|--------|--|
| Note 1: Other Do Note 2: Tiss Note 3: TDI | lication; P = previous er Combined includes: B opler/PWD; B/Power Do ue Harmonic Imaging, T Note 4: 4D Ill Organ: breast, thyroid | /M; B/P ppler/P he feat | WD; B/T WD | HI; M /Co | lor M; B/Co | . , | |
| | Office of <i>In</i> | Division <i>Vitro</i> Di | Division S of Radio agnostics K1301 | ological F and Ra | | lealth | |

Transducer: 2P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clin | Mode of Operation | | | | | | | | |
|---------------------|----------------------------|---|---|-----|----------------|------------------|----------------------|--------------------|-------------------|
| General (TRACK 1 | Specific (TRACKS 1 & 3) | В | М | PWD | CWD | Color Doppler | Power (Amplitude) | Other* Combined | Other* Specify |
| ONLY) | ······ | | | | | | Doppler | <u> </u> | |
| Ophthalmic | Ophthalmic | | | | | | | | T |
| Fetal | Fetal | | | | | | | ļ | |
| Imaging& | Abdominal | Р | Ρ | Р | | P | Р | Note 1 | Notes 2 |
| Other | Intra-operative Specify | | | | | | | | ļ |
| | Intra-operative Neuro | | | | | - | | | |
| , | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | Ρ | Р | P | P | Р | Р | Note 1 | Notes 2,3 |
| | Adult Cephalic | Δ | Р | Р | Р | Р | Р | Note 1 | Notes 2,3 |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | , | | |
| | Trans-esoph (non-Card) | | | | | | | | |
| | Musculo-skeletal | | | | | | | | |
| | (Conventional) | | | | | | | | |
| | Musculo-skeletal | | | | | | | | |
| | (Superficial) | | | | | | · | İ | |
| | Intravascular | | | | | | | | l |
| | Other (Ob/GYN) | | | | | | | | |
| Cardiac | Cardiac Adult | Р | Р | Р | Р | Р | Р | Note 1 | Notes 2,3 |
| | Cardiac Pediatric | Р | Р | Р | Р | Р | Р | Note 1 | Notes 2,3 |
| ٠ | Intravascular(Cardiac) | - | | | | | | | |
| | Trans-esoph (Cardiac) | | | | | - | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral | Peripheral vessel | | | | | | | 1 | |
| Vessel | Other (specify) | | | | - | <u> </u> | | | |

| | , | ,, | 1 | | | | | | L |
|--------------|---|---------------|----------|----------|----------|-------------|-----------------|--------------|---|
| N = new inc | lication; | P = previo | usly cl | eared by | / FDA; | E = a | dded under ti | nis appendix | |
| | er Combined pler/PWD; B | | | | HI; M/Co | olor M; B/C | olor Doppler; I | B/Color | |
| Note 2: Tiss | ue Harmonic | Imaging, Ti | he feati | ire does | not use | contrast a | gents | | |
| Note 3: TDI | Note | 4: 4D | | | • | | | | |
| Note 5: Sma | all Organ: bre | ast, thyroid, | testes | | | | | | |
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(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k)

K130119

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Transducer: 5P1 Phase Array

Diagnostic Ultrasound Transducer

| Cli | nical Application | | | | | Mode o | f Operation | | |
|------------------------------|----------------------------|----------|----------|-----|-----|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | В | м | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal | Fetal | Ĭ | | | | | | | |
| Imaging& | Abdominal | | | | | | | | |
| Other | Intra-operative Specify | i – | | | | 1 | | | |
| | Intra-operative Neuro | Î | | | Ī | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | Р | Р | Р | | Р | Р | Note 1 | Notes 2 |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | Р | Р | Р | Р | Р | Р | Note 1 | Notes 2,3 |
| | Adult Cephalic | <u> </u> | | | | | | | |
| | Trans-rectal | | | | | | - · · · · | | |
| | Trans-vaginal | <u> </u> | | | | | | | |
| | Trans-urethral | | | | ! | | | | |
| | Trans-esoph(non-Card) | | | | | | | | |
| | Musculo-skeletal | T | | | | | | | |
| | (Conventional) | | | | | | | | |
| | Musculo-skeletal | | | | | | | | |
| | (Superficial) | L | <u>.</u> | | | | | | |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | , | | | |
| | Cardiac Pediatric | Р | Р | Ρ. | Р | Р | Р | Note 1 | Notes 2,3 |
| | Intravascular(Cardiac) | | | | | | | | |
| | Trans-esoph.(Cardiac) | Ī | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral | Peripheral vessel | | | | | <u> </u> | | | |
| Vessel | Other (specify) | 1 | <u> </u> | | | | | | |

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Transducer: 6V1 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Appl | ication | Мо | de of | Operation | on | | | | |
|------------------------------|----------------------------|----------|-------|------------|-----|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | В | М | PWD | ÇWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal | Fetal | Г | | | | | | | |
| Imaging& | Abdominal | | | | | | | | |
| Other | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | _ | | | |
| | Small Organ (specify) | | | | | | · | | |
| | Neonatal Cephalic | | | | } | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | Р | P | Р | | Р | Р | Note 1 | Notes 2 |
| | Trans-vaginal | Р | P | P | | Р | Р | Note 1 | Notes 2 |
| | Trans-urethral | | | | | | • | | |
| | Trans-esoph (non-Card) | | | | | | | | |
| | Musculo-skeletal | | | | | | | <u> </u> | |
| | (Conventional) | l | | | | | | | |
| | Musculo-skeletal | | | | | | | | |
| | (Superficial) | | | | | | | l | |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | | | l <u>.</u> | | | | | |
| Cardiac | Cardiac Adult | 1 | | | | | | | _ |
| | Cardiac Pediatric | | | | | · | | | |
| | Intravascular(Cardiac) | | | Ī - | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | <u> </u> | | | | | | | 1 |
| | Other (specify) | | | i | | | | | |
| Peripheral | Peripheral vessel | | | 1 | 1 | | · - | | |
| Vessel | Other (specify) | 1 | | | 1 | | | 1 | |

| | Other (specify) | | | | | | | | |
|--------------|-----------------------------|-------|-------|----------|-----------|--------------|----------------|-------------|---|
| Peripheral | Peripheral vessel | | | | | | , <u>-</u> | | Г |
| /essel | Other (specify) | | | Ĺ | | | | | |
| 1 = new inc | lication; P = previo | usly | cle | ared by | FDA; | E = add | ded under th | is appendix | |
| Note 1: Othe | er Combined includes: B/ | M; E | 3/PW | /D; B/T | H; M/Co | lor M: B/Co | lor Doppler; B | /Color | |
| Dop | pler/PWD; B/Power Dop | pler | /PWI |) | | | | | |
| Note 2: Tiss | ue Harmonic Imaging. Tl | ne fe | eatur | e does i | not use o | contrast age | ents | | |
| Note 3: TDI | Note 4: 4D | | | | | | | | |
| Note 5: Sma | ill Organ: breast, thyroid, | test | es | | | | | | |
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| | | | | | | | | | |
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| | | | (Di | vision S | ign-Off) | | | | |
| | | Divis | ion c | of Radio | logical F | lealth | | | |
| | Office of In | Vitro | Dia | gnostics | and Ra | diological H | lealth | | |
| | | | | | | | | | |

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Transducer: 6V3 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Applic | cation | Мо | de o | f Operation | on | - | | | |
|------------------------------|----------------------------|----|------|-------------|-----|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | В | М | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging& | Fetal Abdominal | | | | | | | | |
| Other | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | Р | Р | Р | | Р | P | Note 1 | Notes 2 |
| | Trans-vaginal | Р | Р | Р | | Р | Р | Note 1 | Notes 2 |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | | |
| | Musculo-skeletal | | | | | | | | |
| | (Conventional) | | ŀ | - | | | | | |
| | Musculo-skeletal | | | | | | | | |
| | (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular(Cardiac) | | | • | | | | - | |
| | Trans-esoph.(Cardiac) | Ĭ | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral | Peripheral vessel | | | | | | | | |
| Vessel | Other (specify) | | | | 1 | | | | |

| | Cardiac Pediainc | ı i | | 1 | |] | 1 | I | |
|-------------------------------------|---|----------------------|------------------------------------|-----------|--|-----------|--------------|-------|---|
| | Intravascular(Cardiac) | | T | | | 1 | | | |
| | Trans-esoph.(Cardiac) | | Ī | | | | | | |
| | Intra-cardiac | | | | | | | | _ |
| | Other (specify) | | | | | | | | |
| Peripheral | Peripheral vessel | | | | Ì | | | | Ξ |
| Vessel | Other (specify) | | | - | | | | | _ |
| N = new ind | ication; P = previo | usly cle | ared by | FDA; | E = a | dded unde | er this appe | endix | _ |
| Dop Note 2: Tissu Note 3: TDI | er Combined includes: B/ opler/PWD; B/Power Dop ue Harmonic Imaging. Th Note 4: 4D Il Organ: breast, thyroid, | pler/PV ie featui | ۷D | | | | ler; B/Color | | |
| | Office of In | ivision | ivision S of Radio agnostics | logical F | lealth | Health | | | |
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Indications for Use Page 6 of 15

Transducer: EC9-5 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Appl | | Мо | de o | f Operati | on | | | | |
|------------------------------|----------------------------|-----|----------|-----------|-----|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | В | м | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal | Fetal | П | | | Ì | | | | |
| lmaging& | Abdominal | | | | | | | | |
| Other | Intra-operative Specify | i - | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | | | | | | | Î | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | Р | Р | Р | | Р | Р | Note 1 | Notes 2 |
| | Trans-vaginal | Р | Р | Р | ĺ | Р | Р | Note 1 | Notes 2 |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | | |
| | Musculo-skeletal | | | | | | | | |
| | (Conventional) | | | | | | | | |
| | Musculo-skeletal | I | | | | | | | |
| | (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular(Cardiac) | | | | | | | | |
| | Trans-esoph (Cardiac) | | | | | | | | |
| | Intra-cardiac | | <u> </u> | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral | Peripheral vessel | | | | | | | | |
| Vessel | Other (specify) | Ī | | | | | | | |

| | • | | | | | 1 | | | |
|--------------|----------------|---------------|-----------|------------|-----------|-------------|---------------|-------------|---|
| /essel | Other (speci | fy) | | | | | | | |
| V = new inc | dication; | P = previ | ously cl | eared by | / FDA; | E = ac | ded under t | his appendi | X |
| Note 1: Oth | er Combined | l includes: I | 8/M; B/P | WD; B/T | HI; M/Co | lor M; B/C | olor Doppler; | B/Color | |
| Dop | opler/PWD; E | 3/Power Do | ppler/PV | VD | | | | | |
| Note 2: Tiss | sue Harmonio | c Imaging. | The feat | ure does | not use | contrast ag | gents | | |
| Note 3: TDI | Note | 4: 4D | | | | | | | |
| Note 5: Sma | ali Organ: bro | east, thyroid | i, testes | | | | | | |
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510(k) <u>K130119</u>

Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

Transducer: C611 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Appl | ication | Mo | de o | f Operat | ion | - | · · · · · · | | |
|------------------------------|----------------------------|----|------|----------|-----|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | В | м | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | i | <u> </u> | | |
| Fetal | Fetal | Π | | | | | | | |
| Imaging& | Abdominal | Р | Р | Р | | Р | Р | Note 1 | Notes 2 |
| Other | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | · | · · · · · · · | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | Р | Р | Р | | Р | Р | Note 1 | Notes 2 |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | Р | Р | Р | Р | Р | P | Note 1 | Notes 2,3 |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | · | | | | | |
| | Trans-urethral | | | | | 1 | | | |
| | Trans-esoph (non-Card) | | | | | | | | |
| | Musculo-skeletal | | | | | | | | |
| | (Conventional) | ļ | | | | | | | |
| | Muscuło-skeletal | | | | | | | | |
| | (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | Р | Р | Р | Р | Р | Р | Note 1 | Notes 2,3 |
| | Intravascular(Cardiac) | | | | | | | | |
| | Trans-esoph (Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | · |
| | Other (specify) | | | | | | • | | <u> </u> |
| Peripheral | Peripheral vessel | | | | | | | | |
| Vessel | Other (specify) | | | | | | | | |

| renpherai | relipheral vessel | 1 | | 1 | | | | 1 |
|--------------|-----------------------------------|----------|------------|-----------|------------|---------------|---------------|---|
| Vessel | Other (specify) | | | | | | | Γ |
| N = new ind | dication; P = previ | ously c | leared b | y FDA; | E≃a | added under | this appendix | _ |
| Note 1: Oth | er Combined includes: E | /M; B/P | WD; B/T | HI; M/C | olor M; B/ | Color Dopplei | r; B/Color | |
| Dop | pler/PWD; B/Power Do | pler/P\ | ٧D | | | | | |
| Note 2: Tiss | ue Harmonic Imaging. ⁻ | he feat | ure does | not use | contrast a | agents | | |
| Note 3: TDI | Note 4: 4D | | | | | | | |
| Note 5: Sma | all Organ: breast, thyroid | , testes | | | | | | |
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510(k) <u>K130119</u>

Indications for Use

Transducer: C362 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Appl | cation | Мо | de o | f Operation | on | | | | |
|------------------------------|----------------------------|----------|------|-------------|-----|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | В | м | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal | Fetal | Р | Р | Р | | Р | Р | Note 1 | Notes 2 |
| Imaging & | Abdominal | Р | Р | Р | | Р | Р | Note1 | Notes 2 |
| Other | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | \Box | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vagiпal | 1 | | | | | | 1 | <u> </u> |
| | Trans-urethral | T | | : | | | | | |
| | Trans-esoph.(non-Card) | \vdash | | | | | | | |
| | Musculo-skeletal | | | | | | | | |
| | (Conventional) | | | | | | | | |
| | Musculo-skeletal | | | | | | | | |
| | (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | Р | Р | Р | | Р | Р | Note1 | Notes 2 |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular(Cardiac) | Γ | | | | | | | |
| | Trans-esoph (Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | 1 |
| | Other (specify) | | | | | | | | |
| Peripheral | Peripheral vessel | | П | | | | · | | |
| Vessel | Other (specify) | | | | | | | | |

| Peripheral | Peripheral vessel | | | ŀ | | | | ī |
|--------------|----------------------------|---------|-------------|----------|-------------|---------------|--------------|---|
| Vessel | Other (specify) | | | | | | | Ĩ |
| N = new ind | dication; P = previo | ously o | leared by | FDA; | E = a | dded under ti | his appendix | |
| Note 1: Othe | er Combined includes: B | /M; B/ | PWD; B/T | HI; M/Co | lor M; B/C | olor Doppler; | B/Color | |
| Dop | pler/PWD; B/Power Dop | pler/P | WD | | | | | |
| Note 2: Tiss | ue Harmonic Imaging. T | he fea | ture does | not use | contrast a | gents | | |
| Note 3: TDI | Note 4: 4D | | | | • | - | | |
| Note 5: Sma | all Organ: breast, thyroid | teste | S | | | | | |
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| | Office of In | VIIIO L | nagnostic: | s and Ra | idiological | Health | | |

510(k) K130119

Transducer: C344 Curved Array

Diagnostic Ultrasound Transducer

| Clinical Appl | ication | Mo | de o | f Operat | ion | | | | |
|------------------------------|-----------------------------------|-----|------|----------|-----|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | В | м | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal | Fetal | Р | Р | Р | | Р | Р | Note 1 | Notes 2 |
| Imaging& | Abdominal | Р | Р | Р | | Р | Р | Note 1 | Notes 2 |
| Other | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | l |
| | Small Organ (specify) | | | | | | , | | |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | • | l | |
| | Trans-esoph.(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | Ü | | | | |
| | Intravascular | | 1 | | | | | | |
| | Other (Ob/GYN) | Р | Р | Р | | Р | P | Note 1 | Notes 2 |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular(Cardiac) | | | | | 1 | | | <u> </u> |
| | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | 1 | | | | | | |
| | Other (specify) | Ī — | | | | | | | |
| Peripheral | Peripheral vessel | | | | | | | | |
| Vessel | Other (specify) | 1 | | | | | | | |

| | Intravascular | • | | | | | | 1 | - I |
|-------------|---|-------|-------------|---------------------|---------|---------------------------------------|--------|---------|---------|
| | Other (Ob/GYN) | Р | Р | Р | | Р | P | Note 1 | Notes |
| Cardiac | Cardiac Adult | | | | | | | 1 | |
| | Cardiac Pediatric | | | | | | | 1 | |
| | Intravascular(Cardiac) | | | | | · · · · · · · · · · · · · · · · · · · | | | |
| | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | 1 |
| Peripheral | Peripheral vessel | | | | | | | | |
| /essel | Other (specify) | | | | | | | " | |
| Note 3: TDI | sue Harmonic Imaging. T Note 4: 4D all Organ: breast, thyroid | | | re does | not use | contrast a | gents | | |
| · | Office of In | Vitro | sion Dia | of Radi agnostic | | Health | Health | | |
| Indications | | ,K) | | K130 ⁻ | 119 | | • | Page 10 |) of 15 |

Transducer: C354 Curved Array

Diagnostic Ultrasound Transducer

| Clinical Appl | | Мо | de o | f Operation | on | | | | |
|------------------------------|----------------------------|----------|------------|-------------|-----|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | В | м | PWD | CMD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal | Fetal | N | N | N | | N | N | Note 1 | Notes 2 |
| Imaging& | Abdominal | N | N | N | | N | N | Note 1 | Notes 2 |
| Other | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | · | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | ŀ | | | | |
| | Trans-esoph.(non-Card) | | [<u> </u> | | | | | } |] |
| | Musculo-skeletal | | | | | | | | |
| | (Conventional) | | | | | | | | |
| | Musculo-skeletal | | | | | | | | |
| | (Superficial) | | | | | | | | |
| | Intravascular | <u> </u> | <u> </u> | <u></u> | | | | | |
| | Other (Ob/GYN) | N | N | N | · | N | N | Note 1 | Notes 2 |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular(Cardiac) | | | | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral | Peripheral vessel | Π | | 1 | | | | | |
| Vessel | Other (specify) | | | | | | | | 1 |

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|--------------|---|-------------|---------|---------|----------|-------------|-------------|---------|----------|---|
| Peripheral | Peripheral vessel | | | | | | | | | Τ |
| Vessel | Other (specify) | | | | | | | | | Ī |
| N = new inc | lication; P = p | reviously | / clear | ed by | FDA; | E = a | dded unde | r this | appendix | |
| Note 1: Othe | er Combined includ | es: B/M; l | 3/PW[|); B/TH | II; M/Cd | olor M; B/C | olor Dopple | er; B/0 | Color | |
| Dop | pler/PWD; B/Powe | r Doppler | /PWD | | | | | | | |
| Note 2: Tiss | ue Harmonic Imagi | ng. The f | eature | does r | ot use | contrast a | gents | | | |
| Note 3: TDI | Note 4: 4D | • | | | | | _ | | | |
| Note 5: Sma | all Organ: breast, th | yroid, tes | tes | | | | | | | |
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| | Office | | | | | adiological | Health | | | |
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Transducer: VC6-2 Curved Array

Diagnostic Ultrasound Transducer

| Clinical Appl | ication | Mode of Operation | | | | | | | | | | |
|------------------------------|----------------------------|-------------------|---|-----|----------|------------------|---------------------------------|--------------------|-------------------|--|--|--|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | В | м | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify | | | |
| Ophthalmic | Ophthalmic | | | | | | | | | | | |
| Fetal | Fetal | Р | Р | Р | | Р | P | Note 1 | Notes 2,4 | | | |
| Imaging & | Abdominal | Р | Р | Р | | Р | Р | Note 1 | Notes 2,4 | | | |
| Other | Intra-operative Specify | | | | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | | | | |
| | Laparoscopic | | | | | | | | | | | |
| | Pediatric | | | | | | | | | | | |
| | Small Organ (specify) | | | | | | | | | | | |
| | Neonatal Cephalic | | | | | | | | | | | |
| | Adult Cephalic | Γ | | | | | | | | | | |
| | Trans-rectal | | | | | | | | | | | |
| | Trans-vaginal | 1 | | | | | | | | | | |
| • | Trans-urethral | | | | | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | | | | | |
| | Musculo-skeletal | | | | | | | | i | | | |
| | (Conventional) | | | | | | | | | | | |
| | Musculo-skeletal | | | | | | | | | | | |
| | (Superficial) | | | | <u> </u> | | | | | | | |
| | Intravascular | | | | | | | | | | | |
| | Other (Ob/GYN) | Р | Р | Р | | Р | Р | Note 1 | Notes 2,4 | | | |
| Cardiac | Cardiac Adult | | | | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | | | | |
| | Intravascular(Cardiac) | | Γ | | | | | | | | | |
| | Trans-esoph.(Cardiac) | L | | | | | | | | | | |
| | Intra-cardiac | | | | | | | | | | | |
| | Other (specify) | | | _ | | | | | | | | |
| Peripheral | Peripheral vessel | | | | | | | | | | | |
| Vessel | Other (specify) | | | | | | | | | | | |

| | Office (Specify) | | | L | | | | |
|--------------|----------------------------|----------|-------------|---------------------------------------|------------|--------------|--------------|-----|
| Peripheral | Peripheral vessel | | | | | | | |
| /essel | Other (specify) | | | | | | | |
| l = new inc | dication; P = previo | ously ci | eared b | y FDA; | Ę = a | idded unde | r this appen | dix |
| Note 1: Oth | er Combined includes: E | /M; B/P\ | ND; B/T | HI; M/C | olor M; B/ | Color Dopple | er; B/Color | |
| Dop | pler/PWD; B/Power Doj | pler/PW | /D | | | | | |
| Note 2: Tiss | ue Harmonic Imaging. 1 | he featu | ire does | not use | contrast a | agents | | |
| Note 3: TDI | Note 4: 4D | | | | | | | |
| Note 5: Sma | all Organ: breast, thyroid | , testes | | | | | | |
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Transducer: L743 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Appli | | Mo | de o | f Operation | on | | | | |
|------------------------------|-----------------------------------|----|------|-------------|-----|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | В | м | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal | Fetal | | | | | | | | |
| Imaging& | Abdominal | | | | | | | | |
| Other | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | Р | Р | Р | | Р | Р | Note 1 | Notes 2 |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | Г | | | | | | | |
| | Trans-rectal | | | - | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | Р | Р | Р | | Р | Р | Note 1 | Notes 2 |
| | Musculo-skeletal (Superficial) | Р | Р | Р | | Р | Р | Note 1 | Notes 2 |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | | | | | | | | |
| Cardiac | Cardiac Adult | | | | ĺ | | | } | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular(Cardiac) | | | | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral | Peripheral vessel | Р | Р | Р | | Р | Р | Note 1 | Notes 2 |
| Vessel | Other (specify) | | | | | | | ĺ | |

| _ | Other (specify) | | | | | | | | | 1 |
|--------------|--------------------|------------|-------|------------|-----------|-----------|-------------|-----------------|-------------|---|
| Peripheral | Peripheral vesse | ! | Р | Р | Р | | Р | Р | Note 1 | Π |
| Vessel | Other (specify) | | | | | | | | | |
| N = new in | dication; P | = previou | usly | r cle | ared by | FDA; | E = ac | dded under th | is appendix | |
| Note 1: Oth | er Combined incl | udes: B/N | M; E | 3/PV | VD; B/T | H; M/Co | lor M; B/C | olor Doppler; E | 3/Color | |
| Do | pler/PWD; B/Po | wer Dopp | oler/ | /PW | D | | | | | |
| Note 2: Tiss | ue Harmonic Ima | aging. Th | e fe | eatu | re does | not use o | contrast ag | gents | | |
| Note 3: TDI | Note 4: 4 | ID. | | | | | | | | |
| Note 5: Sma | all Organ: breast, | thyroid, t | test | es | | | | | | |
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| | Offi | | | | | | diological | Health | | |
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510(k) K130119

Indications for Use

Transducer: L741 Linear Array

Diagnostic Ultrasound Transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Appli | | Mo | de o | f Operat | ion | | | | |
|------------------------------|-----------------------------------|----|----------|----------|---------|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | В | М | PWD | CW D | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal | Fetal | Π | | | | | | | |
| lmaging& | Abdominal | | | | | | | | |
| Other | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | Р | P | P | | Р | Р | Note 1 | Notes 2,5 |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | <u> </u> | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph (non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | Р | Р | P | | Р | Р | Note 1 | Notes 2 |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | <u> </u> |
| | Other (Ob/GYN) | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | 1 |
| | Intravascular(Cardiac) | | | | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral | Peripheral vessel | Р | Р | Р | | Р | Р | Note 1 | Notes 2 |
| Vessel | Other (specify) | 1 | l | | 1 | | | <u> </u> | |

| | Other (specify) | | i | | | | | | 1 |
|--------------|-----------------------------|-------|-------|-----------|----------|-------------|-------------|---------------|------|
| Peripheral | Peripheral vessel | Р | Р | Р | | Р | Р | Note 1 | Not |
| essel | Other (specify) | | | - | | | | | |
| l = new inc | dication; P = previo | usly | / cle | ared by | / FDA; | E = | added unde | er this appen | ıdix |
| Note 1: Oth | er Combined includes: B/ | 'M; E | 3/PV | VD; B/T | HI; M/C | Color M; B | Color Doppl | er; B/Color | |
| Dop | pler/PWD; B/Power Dop | pler | /PW | 'D | • | | | | |
| Note 2: Tiss | ue Harmonic Imaging. Ti | he fe | eatu | re does | not use | e contrast | agents | | |
| Note 3: TDI | Note 4: 4D | | | | | | | | |
| Note 5: Sma | all Organ: breast, thyroid, | test | tes | | | | | | |
| | | | | | | | | | |
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| | | | | | | | | | |
| | | | (D | ivision S | Sign-Off | f) | | | |
| | ſ | Divis | ion | of Radio | ological | Health | | | |
| | Office of In | Vitro | Dia | agnostic | s and F | Radiologica | al Health | | |
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K130119

510(k) _

Transducer: L742 Linear Array

Diagnostic Ultrasound Transducer

| Clinical Appl | | Mo | de o | f Operati | on | | | | · · · · · · · · · · · · · · · · · · · |
|------------------------------|------------------------------------|----------|------|-----------|-----|------------------|---------------------------------|--------------------|---------------------------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | В | М | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | Γ | | | | | | | |
| Fetal | Fetal | | | | | | | | |
| lmaging& | Abdominal | | | | L | | | | |
| Other | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | - | | | | |
| | Pediatric | I | | | | | | | |
| | Small Organ (specify) | Ρ | P | Р | | Р | Р | Note 1 | Notes 2,5 |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | - | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| • | Trans-urethral | | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | Р | Р | Р | | Р | Р | Note 1 | Notes 2 |
| | Musculo-skeletal (Superficial) | Р | Р | Р | | Р | Р | Note 1 | Notes 2 |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular(Cardiac) | <u> </u> | | | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | 1 | |
| | Other (specify) | | | | | | | | |
| Peripheral | Peripheral vessel | Р | Р | Р | | Р | P | Note 1 | Notes 2 |
| Vessel | Other (specify) | | | | | | | | |

| | · · · · · · · · · · · · · · · · · · · | | 1 | | | ì | | 1 | |
|---------------|---------------------------------------|-------|-------|-----------------------------------|-----------------------|-------------|-----------------|------------|---|
| Peripheral | Peripheral vessel | Р | Р | Р | | Р | Р | Note 1 | N |
| Vessel | Other (specify) | | | | | | | | |
| N = new ind | lication; P = previo | usly | cle | ared by | FDA; | E = ad | lded under th | is appendi | x |
| Note 1: Othe | er Combined includes: B/ | M; E | 3/PV | VD; B/TH | ii; M/Col | lor M; B/Co | olor Doppler; E | 3/Color | |
| | pler/PWD; B/Power Dop | | | | • | • | ,, | | |
| Note 2: Tissi | ue Harmonic Imaging. Ti | ne fe | eatur | e does r | not use c | ontrast ag | ents | | |
| Note 3: TDI | Note 4: 4D | | | | | · | | | |
| Note 5: Sma | ll Organ: breast, thyroid, | test | es | | | | | | |
| | Office of <i>In</i> | | ion (| vision Si of Radio gnostics | ign-Off) logical H | | Health | | |